REPORT NUMBER FIFTY-THREE

to the

Secretary

U.S. Department of Health and Human Services

(RE: Part D Prescription Drug Program, Drug Competitive Acquisition Program, Surgical Care Improvement Partnership Program, Physicians Regulatory Issues Team, Physician Fee Schedule and Outpatient Services Proposed Rules, Alliance for Cardiac Care Excellence Program, National Provider Identifier Outreach and Implementation, and other matters)

From the

Practicing Physicians Advisory Council

(PPAC)

Hubert H. Humphrey Building

Washington, DC

August 22, 2005

SUMMARY OF THE AUGUST 22, 2005, MEETING

Agenda Item A — Introduction

The Practicing Physicians Advisory Council (PPAC) met at the Department of Health and Human Services' Hubert H. Humphrey Building in Washington, D.C., on Monday, August 22, 2005 (see Appendix A). The chair, Ronald Castellanos, M.D., welcomed the members of the Council to the 53rd meeting of PPAC. He announced that CMS has updated the PPAC website, which can be found at www.cms.hhs.gov/faca/ppac.

Agenda Item B — Welcome

Tom Gustafson, Ph.D., Deputy Director of the Center for Medicare Management, welcomed the members of the Council and the public. He said the Council plays an important role in the Agency's understanding of the needs and concerns of the physician community.

OLD BUSINESS

Agenda Item C — Update: May 23, 2005, Recommendations and Old Business

Ken Simon, M.D., M.B.A., Executive Director of PPAC, presented the responses from CMS to PPAC recommendations made at the May 23, 2005, meeting (Report Number 52, Presentation 1).

> 52-C-1: PPAC recommends that CMS issue an interim final rule to allow more time for public comments about the Competitive Acquisition Program (CAP).
>
> **CMS Response**: CMS accepted PPAC's recommendation and published an interim final rule on CAP on July 6, 2005. We will be accepting public comments until September 6, 2005.
>
> 52-C-2: PPAC recommends that CMS develop a plan to monitor critical subsets as possible indicators of barriers to access to care, such as new vs. established Medicare patients, patients without Medigap coverage, and specialty vs. primary care physicians, and that CMS develop a plan to address possible declines in access before problems become widespread.
>
> **CMS Response**: CMS is required to report to Congress by July 1, 2008, about CAP implementation. In that report, CMS plans to evaluate the impact CAP has had on access to care, beneficiary satisfaction, and other issues. CMS conducts and monitors environmental scanning through ongoing quarterly meetings with the regional offices to ensure an early warning alert in the event trends emerge that could indicate significant changes.
>
> 52-D-1: PPAC requests that the Physicians Regulatory Issues Team (PRIT) provide more detailed information at the Council's August 2005 meeting on the issue of carriers' reimbursing evaluation and management claims at "half-levels";

further, PPAC recommends that CMS and its carriers use the existing documentation guidelines to determine payment levels rather than arbitrarily assigning other payment levels.

CMS Response: The use of Current Procedural Terminology (CPT) code 99499 can be used when physician documentation is inadequate to support using any of the existing CPT evaluation and management codes. The use of this code has created unanticipated problems with the calculation of the comprehensive error rate testing (CERT) error rate. This issue has been reviewed by the Program Integrity Group. CMS recognizes there may be the occasional circumstance when a clinical service provided to a beneficiary doesn't reach the threshold of a low-level new patient (CPT 99201) or established patient (CPT 99211) visit, at which time CPT code 99499 should be used to describe the service provided. The carriers would determine the appropriate payment for those services when rendered. Any service that reaches or surpasses the 99201 or 99211 threshold would have the usual coding guidelines applied. The infrequency of the use of 99499 would result in such low volume usage of the code that it should not create problems with calculating the CERT error rate.

52-D-2: PPAC requests that PRIT provide the Council with the list it has compiled of drugs that physicians feel are difficult to purchase under the average sales price (ASP) methodology.

CMS Response: We have submitted the drug names, the prices reported by the practitioners, and the best prices we have been able to find to the CMS staff responsible for maintaining the ASP list. They have, in turn, contacted the manufacturers to verify the calculations and data the manufacturers have used to calculate the ASP in question.

52-D-3: PPAC requests that PRIT evaluate the proposed rule for hospital conditions of participation and seek to exclude non-emergency department visits from the requirement to use time stamps.

CMS Response: We are discussing this recommendation with practitioners and attorneys. There is a general feeling that writing the time when a note or order is written requires no additional effort and is a good habit to develop. We will continue to invite comments as we try to develop a sense of the general opinion of the provider community.

52-F-1: PPAC recommends that the evaluation of the recovery audit contractors (RACs) demonstration project weigh the cost of administration of the project by the RACs, CMS, and providers and physicians against the amount of money recouped by the RACs in overpayments.

CMS Response: CMS agrees that evaluation of the RAC demonstration should include a number of factors, including CMS administrative costs, the effect of the demonstration on the provider community including provider administration costs, and the net impact for the Medicare Trust Fund. Additionally, the evaluation includes an analysis of the costs incurred by the RACs themselves and will compare the RAC operations to historical Medicare operations.

52-F-2: PPAC recommends that if a physician or provider successfully appeals a claim determination made by a RAC, the RAC must reimburse the physician or provider for expenses incurred by the appeal.

CMS Response: Financial negotiations with potential bidders concluded in March, and contracts were awarded based on a specific statement of work that did not include this requirement; therefore, CMS is precluded from making this change without renegotiating the RAC contracts and contingency fees. CMS believes it is not in the best interest of the program to enter into a renegotiation process at this time. However, CMS will consider this recommendation in the future.

52-F-3: PPAC recommends that issues related to teaching physician guidelines be excluded from RAC purview for claims determination.

CMS Response: CMS designed the demonstration to closely mirror the current Medicare environment. The RACs must follow all national and local guidelines regarding coverage and payment policies. Therefore, CMS included services provided by teaching physicians.

52-F-4: PPAC recommends that CMS and the RACs notify the provider community of each new area of review, such as review of outpatient claims.

CMS Response: CMS agrees with the recommendation and, to the extent possible, CMS will notify provider communities of new focus areas before the RAC requests medical records or transmits overpayment demand letters. Notification may be via CMS channels of communication, such as the MedLearn articles, or through the state associations.

52-F-5: PPAC recommends that when CMS reviews the RACs' performance, CMS ensures that underpayment issues are evaluated and reported appropriately.

CMS Response: CMS agrees. The RACs report potential underpayments to CMS monthly. Additionally, the evaluation of the RAC demonstration incorporates determined underpayments and the identification methodology.

52-G-1: PPAC recommends that CMS develop a National Provider Identifier (NPI) directory that would be appropriately accessible to providers for the

purposes of claim submission and that the directory include appropriate security measures to protect the data.

CMS Response: CMS agrees in principle but needs to determine Health Insurance Portability and Accountability Act (HIPAA) security requirements. CMS plans to publish 6060-N, Data Dissemination Notice, in the *Federal Register* in October of 2005. This notice will provide the details addressing the procedures that providers and other entities must follow in order to obtain information from the National Plan and Provider Enumeration System (NPPES). Our notice must balance the need for covered entities to obtain NPI data for use in HIPAA standard transactions against Privacy Act and security requirements. We are aware that, in order to complete standard transactions, some providers will need to utilize and thus have some access to the NPI of a referring provider. We are currently looking at the possibility of publication of an NPI registry available to the public. However, unlike the Unique Physician Identification Number (UPIN), the NPIs are the actual billing numbers to be used by all health care providers for all health care plans, and unlimited access to these numbers by the general public could create a significant program vulnerability. Should CMS decide that the publication of an NPI registry is not compatible with security requirements and/or the Privacy Act, we will ensure that CMS-6060-N provides a methodology for providers to obtain these numbers as required.

52-G-2: PPAC recommends that CMS clarify exactly which identifying numbers will be eliminated or replaced by NPIs and which entities need their own NPIs, such as group practices and independent physicians' associations.

CMS Response: CMS agrees in principle. The Implementation Guides for the standard transactions are the authoritative source for determining the situations in which health care providers must be identified in standard transactions. Generally, by the May 23, 2007, compliance date, where a standard transaction requires the identification of a health care provider as such, the NPI will be used in the place of the legacy provider identification. Specifically, as of May 23, 2007, the following current identification numbers will not be used in standard transactions: Provider Identity Number (PIN), National Supplier Clearinghouse (NSC),Online Survey Certification and Retrieval (OSCAR) System, UPIN, and the National Council for Prescription Drug Program (NCPDP). The NPI will replace these previously assigned numbers in all standard transactions, though health plans may continue to use current numbers internally.

The NPI of the individual referring or rendering physician/practitioner will be used as the billing number. Frequently, a variety of providers are identified on a particular claim, especially with regard to institutional providers. Example: In the case of a radiology group, the radiologist who performed the procedure would be the rendering physician and therefore use his/her NPI. The radiology group itself would likely maintain a separate NPI, and that number may appear on the

standard transaction as the billing provider. Further, an alternate provider may be designated for payment, so its NPI would be part of the transaction as well.

Any health care provider who submits standard transactions must apply for and receive an NPI. The Medicare health plan is developing a guideline document which details how the Medicare program envisions the NPI enumeration of its enrolled providers, based on the information in the NPI Final Rule. We expect to make this document public shortly.

52-J-1: PPAC recommends that, at the August 2005 PPAC meeting, CMS provide the Council with an update on its efforts to make beneficiaries aware of the new drug benefit, supply samples of educational materials for beneficiaries and providers, and give detailed information on the formularies to be used.

CMS Response: CMS agrees with the recommendation and forwarded to all of the PPAC Council members the Toolkit for the Part D benefit. An update on our outreach and transition efforts will be reported at the August 22, 2005, meeting. Information concerning the formularies cannot be released before the prescription drug plans post them.

52-K-1: PPAC recommends that CMS require vendors selected through the CAP to absorb the cost of returned drugs or of unusable drugs and that vendors be willing to advance credit for drugs to patients who are not able to pay the copay.

CMS Response: CMS agrees with the PPAC recommendation, and we outlined in the interim final rule that vendors will be responsible for the cost of returning unused drugs to them.

We worked with the Office of the Inspector General (OIG) to craft a policy that allows vendors to provide assistance to beneficiaries who cannot make the coinsurance payments for their drugs. In addition, vendors cannot collect the coinsurance from a beneficiary until the vendor has confirmation that the drug has been administered.

52-K-2: PPAC recommends that CMS require vendors selected through the CAP be willing to provide drugs for off-label use when evidence supports such use; in such cases, vendors may use the established CMS process for determining medical necessity.

CMS Response: CMS agrees. All local and national coverage determinations will continue to be in place under CAP. This will allow physicians to continue to provide drugs for off-label use as long as it is consistent with any existing and relevant local or national coverage determinations.

52-K-3: PPAC recommends that CMS allow individual practicing physicians to select, on a drug-by-drug basis, whether to purchase drugs from vendors participating in the CAP program.

CMS Response: CMS appreciates PPAC's comment, but in order to participate in CAP, vendors are required to offer the full list of drugs in the CAP category, and physicians are required to make a decision to participate in CAP for the entire category of drugs, rather than on a drug-by-drug basis.

52-K-4: PPAC recommends to CMS that prices set by vendors selected through the CAP process not affect the ASP for those who purchase drugs outside of the CAP program.

CMS Response: CMS is sensitive to the potential for CAP prices to affect the ASP. However, we do not have the legal authority to remove the CAP sales from the calculation of the ASP.

52-K-5: PPAC recommends that CMS help affected providers find sources of affordable drugs, and that CMS report to PPAC some mechanism to accomplish this goal, which was recommended by the OIG.

CMS Response: The CAP will provide physicians with an alternative to the ASP-based system in which physicians must buy drugs individually and then bill Medicare for them. Under CAP, physicians will order drugs from an approved vendor, and the vendor will be responsible for acquiring the drug and billing Medicare. In addition, as CMS designed the CAP drug list, we were sensitive to the concerns we have heard about particular drugs physicians have had difficulty acquiring under the ASP system, and we made an effort to include these drugs in the CAP.

52-K-6: PPAC recommends that the CAP be fully implemented for all specialties and all drugs, without limited formularies, regardless of a patient's ability to pay a copay, and with no additional administrative duties or costs to the physician.

CMS Response: CMS agrees. The first round of CAP will take place in one nationwide geographic acquisition area with one category of drugs that encompasses all specialties of physicians. Although we did not include all Medicare Part B drugs in the first round of CAP because certain drugs were very low volume or posed other operational challenges, the 181 drugs included in CAP comprise over 85 percent of Medicare spending on physician injectable drugs. There are no formularies in the CAP, and we encourage vendors to assist beneficiaries with coinsurance payments consistent with the OIG's Guidelines.

52-K-7: PPAC recommends that CMS stipulate that CAP vendors not be allowed to market directly to patients or to sell physician prescribing data to pharmaceutical companies or anyone else without the physician's consent.

CMS Response: An approved CAP vendor is a HIPAA covered entity and is subject to the HIPAA Privacy Rule that governs the use and disclosure of protected health information.

52-K-8: PPAC recommends that physicians be allowed 30 days for submission of verification of administration.

CMS Response: CMS understands PPAC's concern about billing timeframes, but the final rule requires CAP participating physicians to submit a CAP claim within 14 days. Our claims data suggests that this is consistent with the practice patterns of most physicians.

52-K-9: PPAC recommends that the process of prescription submission and claims submission require only limited, essential data (on the basis of the recommendations of specialty societies).

CMS Response: CMS agrees, and the CAP order form and claim will require only information that is essential to filling the order and paying the claim. In addition, once a CAP patient is established with a vendor, subsequent CAP orders will require a more limited set of information. We encourage specialty societies to submit comments to the interim final rule on the data elements. We carefully considered the data included in the drug orders as finalized in the interim final rule. The required data elements may change as our experience with CAP grows.

52-K-10: PPAC recommends that the definition of "emergency" include patient hardship in rescheduling office visits due to a delay in delivering therapy.

CMS Response: CMS disagrees. The interim final rule defines emergency as an unforeseen situation determined by a physician in his or her clinical judgment to require prompt action on the part of the physician to supply the patient with drugs from his or her own stock. The situation also must comply with the other three criteria specified in the statute, i.e., the drugs were required immediately, the physician could not have anticipated the need for the drugs, and the vendor could not have delivered the drugs in a timely manner.

52-M-1: PPAC recommends that CMS support legislation or otherwise devise a system that allows the transfer of money saved from Part A into Part B when savings occur as a result of better outpatient management that results in fewer complications, less hospitalization, or less use of the emergency department.

CMS Response: CMS recognizes the concern and appreciates the potential impact on clinicians. A statutory change would be necessary, and we would consider the possibility of supporting such a change.

52-M-2: PPAC recommends that CMS describe the current methodology proposed to allocate dollars saved from improved performance by providers.

CMS Response: CMS acknowledges the question, but there is no current methodology proposed for the allocation of dollars as there is not a national pay-for-performance program at this time.

Dr. Simon noted that four members of the Council are reaching the completion of their terms, and CMS is currently accepting nominations for PPAC membership. The Council thanked Dr. Simon for his report.

53-C-1: PPAC recommends that CMS again review the Council's recommendation that physicians be allowed 30 days to submit verification of drug administration.

53-C-2: PPAC recommends that CMS share with PPAC at its next meeting an update on the RACs and their efficacy.

NEW BUSINESS

Agenda Item D — Part D Prescription Drug Program

Jeffrey Kelman, M.D., Medical Officer, Center for Beneficiary Choices, noted that the average premium for the drug program will be about $32. He said the formularies that will be offered are more inclusive than CMS had expected, which should make plan selection easier. Dr. Kelman said CMS is working on an Internet program that would allow physicians and beneficiaries to evaluate drug plans in various ways. The Agency continues to seek input on how it can help beneficiaries identify the best plan for them on the basis of the drugs they currently take.

53-D-1: PPAC applauds CMS's efforts to disseminate information about the Part D Prescription Drug Program to the public.

53-D-2: PPAC recommends that CMS work with the OIG to provide definitive guidance on whether manufacturers' patient assistance programs contribute to patients' true out-of-pocket costs.

Agenda Item F — Surgical Care Improvement Partnership (SCIP) Program

David Hunt, M.D., Medical Officer, Office of Clinical Standards and Quality, described the public-private collaborative efforts to identify both processes and outcomes that can be used to measure and improve quality in the operating room (Presentation 2). The goal of the SCIP is to reduce preventable surgical morbidity and mortality by 25 percent in 2010. Dr. Hunt said the SCIP is relying heavily on the work of the Veterans Administration to incorporate risk adjustment into its findings. He said the SCIP aims to create quality assessment tools that include the guidelines of multiple organizations, thereby decreasing redundancy, confusion, and data collection time.

> 53-F-1: PPAC recommends that CMS recognize that data collection is expensive; if it becomes part of the cost of doing business, the expense must be adequately compensated by CMS and other carriers.

Agenda Item G — Competitive Acquisition Program

Amy Bassano, Director, Ambulatory Services, Center for Medicare Management, said the comment period brought forth a number of issues the Agency had not considered, so the implementation of the CAP will be delayed until July 2006 (Presentation 3). Vendors will be responsible for collecting patients' copays, but they may waive that responsibility under certain circumstances determined by the OIG.

> 53-G-1: PPAC recommends that CMS not allow CAP vendors to discontinue provision of drugs covered under the CAP to a patient, regardless of a patient's ability to meet copays.
>
> 53-G-2: PPAC recommends that CMS revise the CAP requirements so that physicians may choose to participate on an individual basis and are not obligated to join as a group.
>
> 53-G-3: PPAC recommends that CMS remove CAP vendor prices in calculating the ASP because such inclusion is duplicative and unfair to physicians who do not participate in CAP.
>
> 53-G-4: PPAC recommends that CMS work with Chairman Bill Thomas of the House Ways and Means Committee to clarify how Congress intended the ASP and CAP to function independently of each other.
>
> 53-G-5: PPAC recommends that CMS reevaluate its contention that working with CAP vendors will not increase the administrative burden of physicians, and that physicians be given 30 days to submit the bill for administration of drugs instead of 14.
>
> 53-G-6: Given that CMS has recognized the increased cost to pharmacists of dispensing drugs and has added 2 percent of ASP to cover pharmacy overhead costs to the ASP plus 6 percent formula, the Council recommends that CMS treat

physicians equitably and add 2 percent of ASP for reimbursing physicians using the ASP plus 6 percent formula and add a dispensing fee for physicians using CAP.

Agenda Item H — Update on the Physicians Regulatory Issues Team

William Rogers, M.D., Director of PRIT and Medical Officer to the Administrator, provided a list of drugs that physicians said have identified as difficult to purchase at ASP (Presentation 4). Dr. Rogers said CMS is reevaluating its policy that claims submitted electronically that are denied can only be resubmitted in paper form. He also noted that CMS is developing software that will allow providers to manipulate the data in the electronic remittance notice. Dr. Rogers outlined the status of other issues under consideration by PRIT.

53-H-1: PPAC recommends that CMS allow electronic resubmission of denied electronic claims.

Agenda Item J — Swearing In of New Member

Leslie Norwalk, Esq., Deputy Administrator of CMS, swore in M. LeRoy Sprang, M.D., and thanked the Council members for providing their real-world perspective. Ms. Norwalk described the five key tenets of prescription drug coverage under the Medicare Modernization Act (MMA): it is voluntary for most beneficiaries, provides catastrophic coverage, covers those with low/limited incomes, allows room for employer-sponsored retiree coverage, and seeks cost containment. She said Medicare will have 9,000 customer service representatives available via the toll-free telephone number (800-MEDICARE) to answer questions about the program, as well as Internet resources and face-to-face meetings in communities around the country. In response to a question about the possible coverage gap (a.k.a. the doughnut hole), Ms. Norwalk said some plans have no gap and some have no deductibles.

Agenda Item K — Physician Fee Schedule and Outpatient Services Proposed Rules

Steve Phillips, Director of Practitioner Services for CMS, said the Agency is proposing a "bottom up" calculation of practice expense relative value units (RVUs) to replace the "top-down" method currently used and will use the data from the AMA's Relative Value Update Committee and the Clinical Practice Expert Panel to determine direct expenses (Presentation 5). The Agency will allow 4 years to make the transition to the new methodology. Mr. Phillips briefly outlined the multiple imaging procedures discount and refinements to malpractice RVUs. He confirmed that the sustainable growth rate (SGR) calculation will result in a 4.3% reduction in the Physician Fee Schedule for 2006.

Jim Hart, Director, Outpatient Services, Center for Medicare Management, explained proposed change s in the Hospital Outpatient Prospective Payment System, specifically MMA requirements to address drug acquisition costs, radiopharmaceuticals, and pharmacy overhead costs (Presentation 6). He also described a payment adjustment for rural sole community hospitals and a hospital-based multiple imaging procedures discount.

53-K-1: PPAC requests that CMS present to PPAC the specific amounts of new money in the SGR that can be attributed to the new benefits resulting from MMA to assess the effect of the new money on reaching the SGR target.

53-K-2: PPAC recommends that CMS present to PPAC its plans to monitor critical subsets as possible indicators of barriers to access to care, such as new vs. established Medicare patients, patients without Medigap coverage, and specialty vs. primary care physicians, and that CMS develop a plan to address possible declines in access before problems become widespread.

53-K-3: PPAC recommends that CMS not institute the 4.3% decrease in the Physician Fee Schedule conversion factor but instead use the Medicare Payment Advisory Commission (MedPAC) recommendation of a 2.7% increase while working to fix the SGR.

53-K-4: PPAC recommends that CMS provide PPAC with a response by December 5, 2005, as to whether incident-to drugs can be removed from the SGR retrospectively using an administrative approach.

53-K-5: PPAC recommends that CMS delay implementation of changes in methodology on practice expenses until the American Medical Association and other specialty societies have an opportunity to review the methodology in more detail and assess the impact.

53-K-6: To facilitate the medical community's review of the new practice expense relative value units, PPAC recommends that CMS provide to PPAC 1) examples of how new values are calculated; 2) actual new practice expense values for each code, in addition to the values for the first year of transition; 3) the source of the data for each specialty; 4) the budget neutrality adjustment applied; and 5) the impact of the changes by specialty. This information should be provided before the changes are implemented and with sufficient time for CMS to consider alternative proposals.

Agenda Item M — Alliance for Cardiac Care Excellence (ACE) Program

David Nilasena, M.D., Medical Officer, Dallas Regional Office of CMS, described the public-private collaboration modeled on the SCIP to improve the quality of cardiac care (Presentation 7). The group has identified four target audiences (health care systems and providers; patients, families, and communities; clinicians; and national drivers of quality, e.g., CMS and the Joint Commission on Accreditation of Healthcare Organizations) and drafted preliminary goals for each.

53-M-1: PPAC recommends that CMS assume an active role to ensure that the ACE program works to reduce cardiovascular health disparities among minorities and increase minorities' access to high-quality cardiovascular care.

Agenda Item N — National Provider Identifier (NPI)Outreach and Implementation

Valerie Hart, Director, Division of Provider Information Planning and Development, said over 100,000 NPIs had been issued so far (Presentation 8). She outlined CMS' plans to educate providers about the NPI and said the Agency is working on guidance to better define parts and subparts. Deborah Auerbach, Project Manager for NPI Implementation, explained that the Agency will begin accepting and using the NPI in stages (Presentation 9). She asked that physicians and others begin considering how they will make the transition within their own offices and in concert with their plans and clearinghouses.

Agenda Item O — Public Testimony

Ardis D. Hoven, M.D., of the American Medical Association expressed concerns about several issues, notably the Physician Fee Schedule and the NPI (Presentation 10). The organization has survey data indicating the proposed reimbursement cuts will result in significant barriers in beneficiaries' access to physicians.

Albert Bothe, Jr., M.D., of the Association of American Medical Colleges suggested that CMS use its administrative authority to mitigate the negative effects of the SGR on physician reimbursement (Presentation 11). He also stated that quality improvement initiatives should take into account the costs of data collection and the possibility of attributing quality of care concerns to the wrong individual.

PPAC also reviewed written testimony of the Medical Group Management Association (Presentation 12) and the American Osteopathic Association (Presentation 13).

Agenda Item P — Wrap Up and Recommendations

Herb Kuhn, Director, Center for Medicare Management, said the Agency, providers, and Congress all agree there are problems with the current system, which suggests that an opportunity exists to find a solution. The Council reviewed the recommendations. Dr. Castellanos adjourned the meeting at 4:30 p.m. Recommendations of the Council are listed in Appendix B.

Report prepared and submitted by
Dana Trevas, Rapporteur

PPAC Members at the August 22, 2005, Meeting

Ronald Castellanos, M.D., *Chair*
Urologist
Cape Coral, Florida

Jose Azocar, M.D.
Internist
Springfield, Massachusetts

Peter Grimm, D.O.
Radiation Oncologist
Seattle, Washington

Carlos Hamilton, Jr., M.D.
Endocrinologist
Houston, Texas

Dennis K. Iglar, M.D.
Family Practice
Oconomowoc, Wisconsin

Joe W. Johnson, D.C.
Chiropractor
Paxton, Florida

Christopher Leggett, M.D.
Cardiologist
Canton, Georgia

Barbara L. McAneny, M.D.
Clinical Oncologist
Albuquerque, New Mexico

Geraldine O'Shea, D.O.
Internist
Jackson, California

Laura Powers, M.D.
Neurologist
Knoxville, Tennessee

Gregory J. Przybylski, M.D.
Neurosurgeon
Edison, New Jersey

M. LeRoy Sprang, M.D.
Obstetrician-Gynecologist
Evanston, Illinois

Robert Urata, M.D.
Family Practitioner
Juneau, Alaska

CMS Staff Present:

Deborah Auerbach, Project Manager,
NPI Implementation
Centers for Medicare &Medicaid
Services

Amy Bassano, Program Director,
Ambulatory Services
Center for Medicare Management

Kelly Buchanan Designated Federal
Official for PPAC
Center for Medicare Management

David C. Clark, R.P.H., Director
Office of Professional Relations
Center for Medicare Management

Dr. Thomas Gustafson, Deputy Director
Center for Medicare Management

Edith Hambrick, M.D., Medical Officer
Hospital and Ambulatory Policy Group
Center for Medicare Management

Valerie Hart, Director
Division of Provider Information
Planning and Development
Centers for Medicare & Medicaid
Services

David Hunt, M.D., Medical Officer
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid
Services

Jeffrey Kelman, M.D., Medical Officer
Center for Beneficiary Choices
Centers for Medicare & Medicaid
Services

Mr. Herb Kuhn, Director
Center for Medicare Management

David Nilasena, M.D., Medical Officer
Dallas Regional Office
Centers for Medicare & Medicaid
Services

Leslie Norwalk, Esq.
Deputy Administrator
Centers for Medicare & Medicaid
Services

Mr. Steve Phillips, Director
Division of Practitioner Services
Center for Medicare Management

Dr. William Rogers, Director
Physicians Regulatory Issues Team
Medical Officer to the Administrator
Centers for Medicare and Medicaid
Services

Dr. Ken Simon, Executive Director,
PPAC
Center for Medicare Management

Public Witnesses:

Ardis D. Hoven, M.D.
American Medical Association

Albert Bothe, Jr., M.D.
Association of American Medical
Colleges

Dana Trevas, Rapporteur
Magnificent Publications

APPENDICES

Appendix A: Meeting agenda
Appendix B: Recommendations from the August 22, 2005, meeting

The following documents were presented at the PPAC meeting on August 22, 2005, and are appended here for the record:

Presentation 1: Practicing Physicians Advisory Council Update
Presentation 2: Surgical Care Improvement Partnership Program
Presentation 3: Competitive Acquisition Program
Presentation 4: PRIT Report
Presentation 5: Physician Fee Schedule
Presentation 6: Hospital Outpatient Prospective Payment System Proposed Rules
Presentation 7: Alliance for Cardiac Care Excellence Program
Presentation 8: National Provider Identifier Outreach
Presentation 9: Fee for Service Implementation Plan
Presentation 10: Written Statement of the American Medical Association to the Practicing Physicians Advisory Council
Presentation 11: Written Statement of the Association of American Medical Colleges to the Practicing Physicians Advisory Council
Presentation 12: Written Statement of the Medical Group Management Association to the Practicing Physicians Advisory Council
Presentation 13: Written Statement of the American Osteopathic Association to the Practicing Physicians Advisory Council

Appendix A

Practicing Physicians Advisory Council
Hubert H. Humphrey Building
Room 705A
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
August 22, 2005

8:30 – 8:40 a.m.	**A. Open Meeting**	**Ronald Castellanos, M.D. Chairman Practicing Physicians Advisory Council**
8:40 – 8:45 a.m.	**B. Welcome**	**Herb Kuhn, Director Tom Gustafson, Ph.D. Deputy Director Center for Medicare Management Centers for Medicare & Medicaid Services**
8:45 – 9:15 a.m.	**C. Update**	**Kenneth Simon, M.D., M.B.A. Executive Director Practicing Physicians Advisory Council**
9:15 - 9:45 a.m.	**D. Part D Prescription Drug Program**	**Jeffrey Kelman, M.D. Medical Officer Center for Beneficiary Choices**
9:45 –.10:00 a.m.	**E. Break (Chair Discretion)**	
10:00 – 10:45 a.m.	**F. Surgical Care Improvement Partnership Program**	**David Hunt, M.D. Medical Officer Office of Clinical Standards And Quality Centers for Medicare & Medicaid Services**
10:45- 11:30	**G. Competitive Acquisition Program**	**Amy Bassano Director, Ambulatory Services, Center for**

		Medicare Management
11:30-12 noon	**H. PRIT Update**	**William Rogers, M.D. Director Physicians Regulatory Issues Team Office of Public Affairs Centers for Medicare and Medicaid Services**
12 noon- 1:00pm	**I. Lunch**	
1:00- 1:30p.m	**J. Swearing in of new member**	
1:30- 2:30 p.m.	**K. Physician Fee Schedule And Outpatient Services Proposed Rules***	**Steve Phillips Director, Practitioner Services and Jim Hart Director, Outpatient Services Center for Medicare Management**
	***** ***Panel Discussion***	
		Edith Hambrick, M.D. Medical Officer Hospital and Ambulatory Policy Group and Carol Bazell, M.D. Medical Officer Hospital and Ambulatory Policy Group Center for Medicare Management
2:30- 2:45 p.m.	**L. Break (Chair discretion)**	
2:45-3:30pm	**M. Alliance for Cardiac Care Excellence Program**	**David Nilasena, M.D. Medical Officer Dallas Regional Office Centers for Medicare & Medicaid Services**

3:30- 4:00 p.m.	**N. NPI- Outreach and Implementation -**	**Valerie Hart** **Director, Division of Provider Information Planning and Development** **and** **Deborah Auerbach** **Project Manager, NPI Implementation** **Centers for Medicare & Medicaid Services**
4:00-4:15 pm	**O. Testimony**	**Ardis D. Hoven, M.D.** **American Medical Association** Albert Bothe, Jr., M.D. Association of American Medical Colleges
4:15–4:45 p.m.	**P. Wrap Up/Recommendations**	**Herb Kuhn** **Director** **Thomas Gustafson, P.hD.** **Deputy Director** **Center for Medicare Management** **Centers for Medicare & Medicaid Services**

Appendix B

PRACTICING PHYSICIANS ADVISORY COUNCIL (PPAC) RECOMMENDATIONS
August 22, 2005

Follow Up to May 23, 2005, Recommendations

53-C-1: PPAC recommends that CMS again review the Council's recommendation that physicians be allowed 30 days to submit verification of drug administration.

53-C-2: PPAC recommends that CMS share with PPAC at its next meeting an update on the Recovery Audit Contractors and their efficacy.

Part D Prescription Drug Program

53-D-1: PPAC applauds CMS' efforts to disseminate information about the Part D Prescription Drug Program to the public.

53-D-2: PPAC recommends that CMS work with the Office of the Inspector General to provide definitive guidance on whether manufacturers' patient assistance programs contribute to patients' true out-of-pocket costs.

Surgical Care Improvement Partnership Program

53-F-1: PPAC recommends that CMS recognize that data collection is expensive; if it becomes part of the cost of doing business, the expense must be adequately compensated by CMS and other carriers.

Competitive Acquisition Program (CAP)

53-G-1: PPAC recommends that CMS not allow CAP vendors to discontinue provision of drugs covered under the CAP to a patient, regardless of a patient's ability to meet copays.

53-G-2: PPAC recommends that CMS revise the CAP requirements so that physicians may choose to participate on an individual basis and are not obligated to join as a group.

53-G-3: PPAC recommends that CMS remove CAP vendor prices in calculating the average sales price (ASP) because such inclusion is duplicative and unfair to physicians who do not participate in CAP.

53-G-4: PPAC recommends that CMS work with Chairman Bill Thomas of the House Ways and Means Committee to clarify how Congress intended the ASP and CAP to function independently of each other.

53-G-5: PPAC recommends that CMS reevaluate its contention that working with CAP vendors will not increase the administrative burden of physicians.

53-G-6: Given that CMS has recognized the increased cost to pharmacists of dispensing drugs and has added 2 percent of ASP to the ASP plus 6 percent formula to cover pharmacy overhead costs, the Council recommends that CMS treat physicians equitably and add 2 percent of ASP for reimbursing physicians using the ASP plus 6 percent formula and add a dispensing fee for physicians using CAP.

Physician Regulatory Issues Team Update

53-H-1: PPAC recommends that CMS allow electronic resubmission of denied electronic claims.

Physician Fee Schedule and Outpatient Services Proposed Rules

53-K-1: PPAC requests that CMS present to PPAC the specific amounts of new money in the sustainable growth rate (SGR) that can be attributed to the new benefits resulting from the Medicare Modernization Act to assess the effect of the new money on reaching the SGR target.

53-K-2: PPAC recommends that CMS present to PPAC its plans to monitor critical subsets as possible indicators of barriers to access to care, such as new vs. established Medicare patients, patients without Medigap coverage, and specialty vs. primary care physicians, and that CMS develop a plan to address possible declines in access before problems become widespread.

53-K-3: PPAC recommends that CMS not institute the 4.3% decrease in the Physician Fee Schedule conversion factor but instead use the Medicare Payment Advisory Commission (MedPAC) recommendation of a 2.7% increase while working to fix the SGR.

53-K-4: PPAC recommends that CMS provide PPAC with a response by December 5, 2005, as to whether incident-to drugs can be removed from the SGR retrospectively using an administrative approach.

53-K-5: PPAC recommends that CMS delay implementation of changes in methodology on practice expenses until the American Medical Association and other specialty societies have an opportunity to review the methodology in more detail and assess the impact.

53-K-6: To facilitate the medical community's review of the new practice expense relative value units, PPAC recommends that CMS provide to PPAC 1) examples of how new values are calculated; 2) actual new practice expense values for each code, in addition to the values for the first year of transition; 3) the source of the data for each specialty; 4) the budget neutrality adjustment applied; and 5) the impact of the changes by specialty. This information should be provided before the changes are implemented and with sufficient time for CMS to consider alternative proposals.

Alliance for Cardiac Care Excellence (ACE) Program

53-M-1: PPAC recommends that CMS assume an active role to ensure that the ACE program works to reduce cardiovascular health disparities among minorities and increase minorities' access to high-quality cardiovascular care.